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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,017	01/23/2006	Torsten Muller	B1180/20045	4395

3000 7590 04/28/2008

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EXAMINER	
RAMDHANIE, BOBBY	
ART UNIT	**PAPER NUMBER**
1797	

NOTIFICATION DATE	DELIVERY MODE
04/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/556,017	MULLER ET AL.	
	Examiner	Art Unit	
	BOBBY RAMDHANIE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-29* is/are pending in the application.

4a) Of the above claim(s) *21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-20,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/22/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 9-20, 28 & 29 drawn to a particle injector.

Group II, claim(s) 21-27, drawn to a microfluidic system comprising a particle injector.

1. The inventions listed as Groups I & II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature. The following reason is why: The common technical feature, the particle injector of Groups I-II, does not make a contribution over the prior art of record. See Hansen (US6400453), Sklar et al (US2003/040105), or see Lefevre et al (US5138181).

During a telephone conversation with Mr. David Tener on 03/03/08, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-7, 9-20, 28 & 29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7, 9, 10, 14-18, 20, & 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Sklar et al (US20030040105).

6. Applicants' claims are toward a particle injector.

7. Regarding Claims 1-4, 7, 9, 10, 14-18, 20, & 29, Sklar et al discloses a particle injector for introducing particles into a carrier flow of a microfluidic system (See Abstract), comprising: A) At least one inlet for receiving the carrier flow (See Abstract), B) At least one outlet for discharging the carrier flow with the introduced particles (See Abstract), C). At least one carrier flow connecting the inlet to the outlet (See Abstract), wherein the carrier flow channel has substantially no dead volume ([0110] and [0111]), and D). At least one injection channel terminating in the carrier flow channel for introducing the particles into the carrier flow, wherein the injection channel has a cross-section narrowing to the carrier flow channel the carrier flow channel has substantially no dead volume (See Figure 3; narrowing of the channels & [0110] and [0111]). Additional disclosures included: A). Claim 2: Wherein the injection channel terminates obtusely in the carrier flow (See Figure 7. Obtuse is taken as not sharp); B). Claim 3: Wherein the injection channel terminates substantially right-angled in the carrier flow (See Figure 7; Channels are substantially right angled & See [0074] which specifically disclosed a T shaped junction which defines right angles); Claim 4: Wherein the inlet and the outlet have a substantially same-size cross-section (See Figure 7; inlet and outlet have substantially the same sized cross section); Claim 7: Wherein the injection channel is arranged on a top side (See Figure 1 Item 106 & [0079] the probe is

disclosed as being lowered which implies the particle injector is on a top side); Claim 9: Wherein the injection channel has a cross-section, which widens away from the inlet towards the outlet (See Figure 4; Specifically as the to inlet channels merge to for the outlet channel); Claim 10: Wherein the inlet of the carrier flow channel is located on an underside and the outlet of the carrier flow channel is located on a top side (See Figure 2; Inlet port 220; Outlet port 234); Claim 14: Wherein the carrier flow channel has a substantially shoulder-free inner contour (See Figure 7; All channels are substantially shoulder-free); Claim 15: Wherein the carrier flow channel has a volume of between 0.02 μL and 1 ml (See [0006]); Claim 16: Wherein the particle injector is adapted to be autoclaved (See [0098]; the probe may be made of materials such as tetrafluoroethylene or polyether ether ketone (PEEK)); Claim 17: Wherein the particle injector at least partially comprises a material selected from the group consisting of polyether ether ketone (See [0098]), LEXAN®, ceramic and metal; Claim 18: Wherein the particle injector at least partially comprises a heat-conductive material (See [0098]; Silicone is a heat conductive material); Claim 20: Wherein at least one of any one of the inlet and the outlet has a thread for attaching a line (See [0110]; male and female screws define threads); and Claim 29: Wherein the particle injector is adapted to inject biological cells into the carrier flow of a cell sorter (See [0106]):

8. Claims 1, 5, 6, & 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lefevre et al (US5138181).

9. Applicants' claims are toward a particle injector.

10. Regarding Claims 1, 5, 6, & 28, Lefevre et al discloses a particle injector for introducing particles into a carrier flow of a microfluidic system (See Figure 1; Item 16 or Item 10), comprising: A) At least one inlet for receiving the carrier flow (See Figure 1 the combination of Item 16 and Item 20; or the combination of Item 10 and Item 19), B) At least one outlet for discharging the carrier flow with the introduced particles (See Figure 1 Item 12; orifice), C). At least one carrier flow connecting the inlet to the outlet (See Figure 1 Item 14), wherein the carrier flow channel has substantially no dead volume (See Column 5 lines 54-58; elimination of micro-bubbles defines no dead volume) and D). At least one injection channel terminating in the carrier flow channel for introducing the particles into the carrier flow, wherein the injection channel has a cross-section narrowing to the carrier flow channel the carrier flow channel has substantially no dead volume (See Figure 1 Item 10; narrowing of the flow channel exists in the region of Item 18 & See Column 5 lines 54-58). Additional disclosures included: Claim 5: Wherein the inlet has a centering aid to arrange a line coaxially to the carrier flow channel on the inlet (See Figure 1 Item 10; centering aid & Items 19 & 14 both may define a carrier flow channel); Claim 6: Wherein the centering aid comprises a substantially hollow-cylindrical take-up, which borders the carrier flow channel and is arranged coaxially to the carrier flow whereby the inner diameter of the take-up is larger by the wall thickness of the line than the inner diameter of the carrier flow (See Figure 1 Item 10); Claim 28: Wherein the outlet has a centering aid to arrange a line coaxially to the carrier flow channel on the outlet (See Figure 1 Item 10).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in view of Müller et al.

14. Regarding Claim 19. Sklar et al discloses the particle injector as claimed in Claim 18, except wherein the particle injector is connected with at least one of a temperature sensor or a tempering element. Sklar et al does however disclose that the particle injector may be used with mammalian cells (eukaryote cells are a type of mammalian cells; See [0106]). Müller et al et al discloses a particle injector with two tempering elements (See Abstract) that may be used with eukaryote cells. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Sklar et al with Müller et al et al because according to Müller et al et al, the tempering elements are designed to focus, trap and separate eukaryotic cells (See Abstract).

15. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sklar et al in view of Crane (US5489506).

16. Regarding Claim 11, Sklar et al discloses the particle injector of Claim 1, except wherein the injection channel has a feeding in-aid for an injection needle. Crane discloses this feature (See Figure 2 Item 42; Septum). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the particle injector of Sklar et al with Crane and include a feeding-in aid because according to Crane, the septum provides a tight seal around the needle thereby preventing air, foreign material, or any microorganisms from contaminating the system (See Column 5 lines 53-59).

17. For Claim 12, the combination of Sklar et al and Crane disclose the particle injector of Claim 11, except wherein the feeding-in aid has funnel-shaped cross-section widening of the injection channel. Crane does however disclose a particle injector with a septum which is flexible and moldable. Crane also discloses a particle injector with a needle with a funnel shape at the top end (See Figure 2 Item 42 and Item 38; Septum and Funnel) It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the shape form of the needle with the septum of the particle injector since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works,* 150 U.S. 164 (1993).

18. In addition, it would have been obvious to one of ordinary skill in the art to integrate the funnel shape needle and septum together since Crane discloses the

purpose of the septum is specifically to prevent air from entering the particle injector, integrating these two parts would eliminate potential sources of air or other contaminations from entering the particle injector.

19. For Claim 13, the combination of Sklar et al discloses the particle injector as claimed in Claim 11. Crane further discloses wherein the feeding in-aid comprises a detachably attached separate component, in which a funnel-shaped feed opening is arranged, said opening terminating in the injection channel in a mounted state (See Figure 2 Items 42 & 38); the septum is moldable to the shape of the needle and by pushing the needle further into the septum, the needle would take the form of the funnel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to push the needle down further into the septum to prevent the needle from being bent or broken.

Claim Rejections - 35 USC § 112

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 7, 10 & 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. Regarding Claim 7, Claim 7 recites a particle injector where the injection channel is arranged on top side. It is unclear where the top side is located since the claim is only toward a particle injector.

23. For Claim 10, Claim 10 recites the carrier flow channel is located on the underside and the outlet of the carrier flow channel is located on a top side. It is unclear where the top side is located since the claim is only toward a particle injector.

24. For Claim 17, Claim 17 recites the trademark/trade name Lexan®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polycarbonate and, accordingly, the identification/description is indefinite.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bobby Ramdhanie, Ph.D./
Examiner, Art Unit 1797
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